

Administrative Procedures – Final Proposed Rule Filing

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

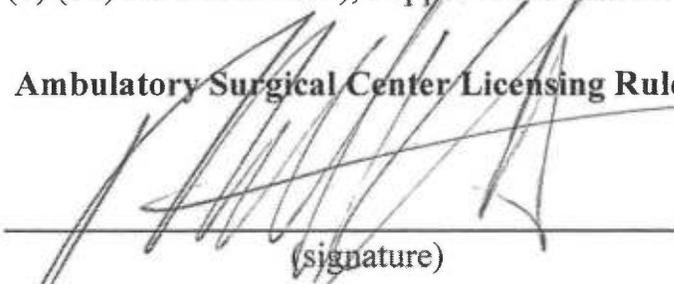
All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of “Proposed Rule Postings” online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Ambulatory Surgical Center Licensing Rule

 on 2-12-20
(signature) (date)

Printed Name and Title:
Michael K. Smith
Secretary
Agency of Human Services

RECEIVED
FEB 13 2020

BY:
RECEIVED BY: _____

- Coversheet
- Adopting Page
- Economic Impact Analysis
- Environmental Impact Analysis
- Strategy for Maximizing Public Input
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)
- ICAR Minutes
- Copy of Comments
- Responsiveness Summary

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE

19P-079

3. ADOPTING AGENCY:

Department of Health

4. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Shayla Livingston

Agency: Department of Health

Mailing Address: 108 Cherry Street, Burlington VT 05401

Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:

<https://www.healthvermont.gov/about-us/laws-regulations/public-comment>

5. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Brendan Atwood

Agency: Department of Health

Mailing Address: 108 Cherry Street, Burlington VT 05401

Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

6. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

3 V.S.A. §801(b)(11), 18 V.S.A §§ 102 and 2159.

EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

18 V.S.A § 2159 states that:

8. "The Department of Health shall adopt rules pursuant to 3 V.S.A. chapter 25 as needed to carry out the purposes of this chapter."
9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.
10. THE AGENCY HAS NOT INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
12. THE AGENCY HAS NOT INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
13. THE AGENCY HAS NOT INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
14. **CONCISE SUMMARY (150 WORDS OR LESS):**
This rule establishes licensure requirements for ambulatory surgical centers.
15. **EXPLANATION OF WHY THE RULE IS NECESSARY:**
This rule establishes the process by which an ambulatory surgical center can apply for a license in Vermont.
16. **EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:**
This rule sets forth the process by which an ambulatory surgical center applies for a license pursuant to 18 V.S.A § 2159, and does not add any additional requirements.
17. **LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:**
Ambulatory surgical centers.

18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

Any burdens in the rule beyond those imposed by the statute are would not have a discernable economic impact.

19. A HEARING WAS HELD.

20. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 1/3/2020

Time: 10:00 AM

Street Address: 108 Cherry Street, Burlington, VT Room 2A

Zip Code: 05401

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

1/10/2020

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

ambulatory surgical center

surgery

license

Administrative Procedures – Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. ADOPTING AGENCY:

Department of Health

3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

- **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
- **NEW RULE** - A rule that did not previously exist even under a different name.
- **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

This filing is **A NEW RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: November 13, 2019, Pavilion Building, 5th floor conference room, 109 State Street, Montpelier, VT 05609

Members Present: Steve Knudson (serving as chair), Dirk Anderson, Shayla Livingston, John Kessler, Matt Langham, and Jennifer Mojo (via phone)

Members Absent: Brad Ferland, Diane Bothfeld, Ashley Berliner and Clare O'Shaughnessy

Minutes By: Melissa Mazza-Paquette

- 2:03 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the October 14, 2019 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- No public comments made.
- Presentation of Proposed Rules on pages 2-6 to follow.
 1. Rule 3.700, Pole Attachments, Public Utility Commission, page 2
 1. Business Name Registration Rules, Office of the Secretary of State, page 3
 2. Central Filing System Rules, Office of the Secretary of State, page 4
 3. Rule Governing Outage Reporting Requirements for Originating Carriers and Electric Power Companies, Vermont Enhanced 911 Board, page 5
 4. Ambulatory Surgical Center Licensing Rule, Department of Health, page 6
- Next scheduled meeting is December 9, 2019 at 2:00 p.m.
- 3:12 p.m. meeting adjourned.

**Proposed Rule: Ambulance Surgical Center Licensing Rule, Department of Health
Presented by Shayla Livingston**

Motion made to accept the rule by John Kessler, seconded by Dirk Anderson, and passed unanimously, except for Shayla Livingston who abstained, with the following recommendations:

1. Proposed Rule Coversheet, page 3, #12: Clarify “are minimal” and “discernable”.
2. Text 6.2: Consider numbering bullets for consistency.

Administrative Procedures – Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. ADOPTING AGENCY:

Department of Health

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

Ambulatory surgical centers: no cost.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

None .

Economic Impact Analysis

5. **ALTERNATIVES:** *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

Not applicable.

6. **IMPACT ON SMALL BUSINESSES:**

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

None.

7. **SMALL BUSINESS COMPLIANCE:** *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

Not applicable.

8. **COMPARISON:**

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

Without this rule ambulatory surgical centers would still be required by law to have a license to operate and to pay a fee to the Department, but would not have a process by which to do so.

9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*

There is no economic impact of this rule, so this is sufficient.

Administrative Procedures – Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. ADOPTING AGENCY:

Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
None .

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
None .

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
None .

6. RECREATION: *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*
None .

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
None .

Environmental Impact Analysis

8. **OTHER:** *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*

None.

9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*

Not applicable.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. ADOPTING AGENCY:

Department of Health

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

Seek stakeholder feedback, provide a public hearing and hold a public comment period.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

The Health Department sent a draft of the proposed changes to the 2018 Ambulatory Surgical Center Working Group for input.

There was a public hearing held at the Department of Health. This rule was posted on the Health Department website: <https://www.healthvermont.gov/about-us/laws-regulations/public-comment>

Hard copies of the rule were made available to the public by contacting the Health Department at 802-863-7280.

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Ambulatory surgical centers, health care quality professionals, the Office of the Health Care Advocate,

Public Input

the Vermont Association of Hospitals and Health Care
Systems.

Administrative Procedures – Incorporation by Reference

THIS FORM IS ONLY REQUIRED WHEN INCORPORATING MATERIALS BY REFERENCE. PLEASE REMOVE PRIOR TO DELIVERY IF IT DOES NOT APPLY TO THIS RULE FILING:

Instructions:

In completing the incorporation by reference statement, an agency describes any materials that are incorporated into the rule by reference and how to obtain copies.

This form is only required when a rule incorporates materials by referencing another source without reproducing the text within the rule itself (e.g. federal or national standards, or regulations).

Incorporated materials will be maintained and available for inspection by the Agency.

1. TITLE OF RULE FILING:

Ambulatory Surgical Center Licensing Rule

2. ADOPTING AGENCY:

Department of Health

3. DESCRIPTION (*DESCRIBE THE MATERIALS INCORPORATED BY REFERENCE*):

Code of Federal Regulations for Ambulatory Surgical Centers

4. FORMAL CITATION OF MATERIALS INCORPORATED BY REFERENCE:

42 CFR § 416.40-416.54

5. OBTAINING COPIES: (*EXPLAIN WHERE THE PUBLIC MAY OBTAIN THE MATERIAL(S) IN WRITTEN OR ELECTRONIC FORM, AND AT WHAT COST*):

free online at: https://ecfr.io/Title-42/cfr416_main

6. MODIFICATIONS (*PLEASE EXPLAIN ANY MODIFICATION TO THE INCORPORATED MATERIALS E.G., WHETHER ONLY PART OF THE MATERIAL IS ADOPTED AND IF SO, WHICH PART(S) ARE MODIFIED*):

Run Spell Check

Chapter 2 – Hospital and Medications Rules

Subchapter 8 –

Ambulatory Surgical Center Licensing Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 2159.

2.0 Purpose

This rule sets forth the standards that apply to the licensing of Ambulatory Surgical Centers in Vermont. This rule applies to all Ambulatory Surgical Centers in Vermont as defined in 18 V.S.A. Chapter 49.

3.0 Definitions

3.1 “Accreditation” means the formal recognition by an CMS-approved accrediting body such as the Joint Commission that indicates conformity with the accrediting body’s required set of standards and criteria.

3.2 “Ambulatory Surgical Center” means any distinct entity that operates primarily for the purpose of providing surgical services to patients not requiring hospitalization and for which the expected duration of services would not exceed 24 hours following an admission. The term does not include:

3.2.1 A facility that is licensed as part of a hospital; or

3.2.2 A facility that is used exclusively as an office or clinic for the private practice of one or more licensed health care professionals, unless one or more of the following descriptions apply:

3.2.2.1 The facility holds itself out to the public or to other health care providers as an ambulatory surgical center, surgical center, surgery center, surgicenter, or similar facility using a similar name or a variation thereof;

3.2.2.2 Procedures are carried out at the facility using general anesthesia, except as used in oral or maxillofacial surgery or used as used by a dentist with a general anesthesia endorsement from the Board of Dental Examiners; or

3.2.2.3 Patients are charged a fee for the use of the facility in addition to the fee for the professional services of one or more of the health care professionals practicing at the facility.

3.3 “CMS” means the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.

3.4 “CMS Conditions for Coverage for Ambulatory Surgical Center” or “CfCs” means the following current Centers for Medicare and Medicaid Services rules

from the Code of Federal Regulations (CFR) and related laws and regulations, interpretive guidelines, appendices and requirements, including 42 CFR § 416.40-416.54.

- 3.5 “Commissioner” means the Commissioner of the Vermont Department of Health.
- 3.6 “Deemed Status” means the status granted to an Ambulatory Surgical Center by a CMS-approved national accrediting body, such as The Joint Commission, after it has surveyed the Ambulatory Surgical Center and determined it is in compliance with all CMS Conditions for Coverage.
- 3.7 “Deficiency” means a policy, procedure, practice or any other action by an Ambulatory Surgical Center that results in the Ambulatory Surgical Center not being in compliance with this rule or with the CMS Conditions for Coverage.
- 3.8 “Department” means the Vermont Department of Health.
- 3.9 “The Joint Commission” means the independent not for profit organization that accredits and certifies that healthcare organizations meet certain performance standards.
- 3.10 “Patient Complaint” means any expression of dissatisfaction related to the care and treatment provided by an Ambulatory Surgical Center, from a patient or the patient’s representative. In this Rule, the term includes patient “grievance” which in the CfCs and CMS State Operations Manual specifically refers to complaints presented to and resolved or attempted to be resolved within the Ambulatory Surgical Center’s internal system.
- 3.11 “Plan of Correction” means a written plan that a licensee is required to submit to address any identified Deficiency to bring an Ambulatory Surgical Center into compliance with this rule.
- 3.12 “State Survey Agency” means the unit of Vermont state government designated by CMS to enforce the federal CfC for Ambulatory Surgical Centers in Vermont.
- 3.13 “Validation Survey” means a survey conducted by the State Survey Agency on behalf of CMS to ensure that an Ambulatory Surgical Center with Deemed Status is in compliance with the Conditions for Coverage.

4.0 Application for an Ambulatory Surgical Center License

- 4.1 No organization or individual may establish, conduct, or maintain operation of an Ambulatory Surgical Center in Vermont without being granted a license by the Department.

- 4.2 Every Vermont Ambulatory Surgical Center license shall expire on December 31 of each year unless otherwise revoked.
- 4.3 An application for an Ambulatory Surgical Center license or license renewal must be submitted in the form required by the Department and available on its webpage. Renewal applications must be submitted on or before the deadline set by the Department.
- 4.4 The application must contain all information required by the Department and be accompanied by a license fee in the amount required by law and posted on the Department webpage. The required information must include:
 - 4.4.1 Identifying information and all facility locations.
 - 4.4.2 Administrative officers and contact information for the person completing the application.
 - 4.4.3 Type of Ambulatory Surgical Center, form of organization, and CMS designation.
 - 4.4.4 Certification and accreditation status.
 - 4.4.5 Number of surgical procedure rooms.
 - 4.4.6 The Ambulatory Surgical Center's publicly accessible policy for providing charity care to eligible patients.
 - 4.4.6.1 At a minimum, such a policy must inform patients of how to apply and identify the criteria used for making decisions on applications.
 - 4.4.7 Documentation of at least one emergency medical service transportation agreement.
 - 4.4.8 Any other information as required by the Department.
- 4.5 Unless the Department specifies a different time or format for response, an Ambulatory Surgical Center must furnish all information requested by the Department within ten (10) working days of receipt, including any documents necessary to verify that the applicant Ambulatory Surgical Center has met the requirements of the CfCs.

5.0 Requirements for Ambulatory Surgical Center Licensure

- 5.1 **42 CFR § 416.40-416.54 is hereby incorporated by reference.**

To be licensed and retain licensure in Vermont, each Ambulatory Surgical Center must comply with all applicable CMS Conditions for Coverage or be operating under a Plan of Correction as described in Section 7.0 of this rule.

5.2 Compliance with CMS Conditions for Coverage for entities without Deemed Status

5.2.1 A Vermont Ambulatory Surgical Center that does not have deemed status must be available for a comprehensive, on-site and unannounced survey by the State Survey Agency to demonstrate compliance with CfCs:

5.2.1.1 Occurring on average once every three years or at a frequency determined by CMS for ambulatory surgical centers without deemed status.

5.2.1.2 Whenever the Department or its designee determines that a survey is required as referenced in Section 7 of this rule.

5.3 Demonstrating Compliance with CMS CfCs through Deemed Status

5.3.1 Ambulatory Surgical Centers accredited by a CMS-approved accrediting body and with Deemed Status meet the compliance requirements of the CfCs; each Accredited Ambulatory Surgical Center with Deemed Status shall be considered by the State Survey Agency and the Department to have met the CfCs unless and until their accreditation is revoked or cancelled or there is a finding made pursuant to Section 7 of this rule.

5.3.2 An Ambulatory Surgical Center with Deemed Status must make the institution available for a Validation Survey by the State Survey Agency when CMS requires a Validation Survey.

5.4 Safety and Quality Programs

5.4.1 Each applicant for an Ambulatory Surgical Center license or renewal must certify compliance with the Patient Safety Surveillance and Improvement System regulations adopted by the Commissioner pursuant to 18 V.S.A. Ch. 43a.

5.4.2 Each Ambulatory Surgical Center must participate in the CMS Ambulatory Surgical Center Quality Reporting Program.

5.4.3 Any Ambulatory Surgical Center that is notified by CMS of a reduction in the ASC annual payment rate or denial of the full annual update to the ASC annual payment rate must submit notice of such action to the Department within fifteen days of receipt of notice from CMS.

5.5 Emergency Preparedness Planning

All Vermont Ambulatory Surgical Centers must comply with CMS regulations for Emergency Preparedness. An Ambulatory Surgical Center must provide a copy of its Emergency Preparedness Plan to the Department for review if requested.

5.6 License Transfer and Posting

5.6.1 An Ambulatory Surgical Center license is not transferable or assignable and must be issued only for the premises and persons named in the application. A licensed Ambulatory Surgical Center changing ownership or eliminating or significantly reducing clinical services must provide at least ninety (90) days advance notice to the Department.

5.6.2 The Ambulatory Surgical Center license must be posted in a conspicuous place on the licensed facility's premises.

6.0 Ambulatory Surgical Center Response and Management of Complaints

6.1 Patients' Rights

Each Vermont Ambulatory Surgical Center must:

6.1.1 Distribute to all patients registered for a procedure a clear language and easily readable print copy of the patient's rights required by 42 CFR 416.50.

6.1.2 Post conspicuously a written version of the patient's rights in areas frequented by patients and patient representatives and on its website.

6.2 Procedures for Responding to Patient Complaints

The following information must be included with the patient's rights distributed to each patient receiving care at a Vermont Ambulatory Surgical Center:

6.2.1 A description of the procedure for filing and appealing a complaint to the Ambulatory Surgical Center, clearly labeled, "To file a complaint" or "What to do if you are not satisfied with our response to your complaint". Other descriptors such as "patient concerns" or "consumer feedback" may be used, but only in addition to "To file a complaint" or "What to do if you are not satisfied with our response to your complaint."

6.2.2 A notice that a complainant may also contact the Department, the Vermont Office of the Healthcare Advocate, the Board of Medical Practice, or the licensing authorities for other health care professions as an alternative. The notice must include the address and phone numbers for the Department, the Board of Medical Practice, the Vermont Office of the Healthcare Advocate, and the Office of Professional Regulation.

- 6.2.3 A published time frame for processing and resolving complaints and appeals within the Ambulatory Surgical Center.
- 6.2.4 A description of internal procedures for receiving, processing and resolving complaints from or filed on behalf of patients. Such procedures must ensure that the Ambulatory Surgical Center complies with the CfC requirements for grievances.
- 6.2.5 Each Ambulatory Surgical Center applicant shall demonstrate to the Department that the Ambulatory Surgical Center meets the following:
 - 6.2.5.3 Maintains adequate records of patient complaints and their resolution; and
 - 6.2.5.4 Documentation that the Ambulatory Surgical Center complies with all other applicable requirements pertaining to patients' rights.

6.2 Reporting Complaint Data

No less frequently than annually, on a schedule and in a format determined to the Commissioner, an Ambulatory Surgical Center must submit to the Department a report summarizing, in aggregate, the types of complaints filed with the Ambulatory Surgical Center by patients or their representatives in the past year. The report must contain:

- 6.2.1 The number of patients served during the reporting period;
- 6.2.2 The total number of complaints received;
- 6.2.3 The total number of complaints in each of the categories the Ambulatory Surgical Center uses to track complaints; and
- 6.2.4 A brief narrative report describing examples of actions taken to resolve complaints in the past year.

7.0 Compliance

- 7.1 Notwithstanding a CMS-approved national accrediting body's determination that an Ambulatory Surgical Center has met CfCs through surveys or Deemed Status, the Department or its designee may independently review or investigate an Ambulatory Surgical Center and determine whether it is in compliance with requirements for Ambulatory Surgical Center licensure under Vermont law.
- 7.2 When notified of a Deficiency, an Ambulatory Surgical Center must within 30 days, or such shorter period as may be specified in the notice for good cause, develop and submit a Plan of Correction for addressing any identified Deficiency and for achieving compliance with this rule.
- 7.3 Department Review and Response to Plan of Correction

7.3.1 Within thirty (30) days after receipt of a Plan of Correction, the Department must notify the Ambulatory Surgical Center of one of the following actions related to each identified Deficiency:

7.3.1.1 Accept the Plan of Correction

7.3.1.2 Request a revision to the Plan of Correction specifying the reasons for the request.

7.3.2 An Ambulatory Surgical Center required to submit a revised Plan of Correction pursuant to Section 7.3.1.2 of this rule must develop and submit the revision within thirty (30) days.

7.3.3 If, after reviewing a revised Plan of Correction, the Department determines that an Ambulatory Surgical Center is not in full compliance with this rule or cannot comply with this rule or the Ambulatory Surgical Center's Plan of Correction, the Department may find that it is in violation of this regulation and proceed with a compliance action.

8.0 Process for Compliance Actions

8.1 The Department may condition, suspend, or revoke the license of an Ambulatory Surgical Center upon due notice and opportunity for hearing with the Commissioner or designee for violation of any provision of this rule or applicable state regulation, municipal ordinance or state statute, pursuant to the provisions of 3 V.S.A. § 814.

8.2 The Department must notice the licensee by registered mail or personal service of the facts that warrant conditioning, suspending, or revoking the license and the right to a hearing. A hearing must be set not less than 60 days from the date of the mailing to or service on the licensee, however a hearing may take place earlier upon agreement of all parties.

9.0 Process for Conditioning or Denying a License Application

9.1 When the Department determines that a license should not be granted without the imposition of specified conditions it may notify the applicant and, if the applicant consents, a license may be issued subject to such conditions.

9.2 When the Department denies an application for licensure, the applicant must be afforded an opportunity for a hearing with the Commissioner or designee pursuant to the provisions of 3 V.S.A. § 814.

9.3 The Department must provide an applicant with notice of denial by mail or by personal service that explains the facts that warrant the denial of the application and the right to a hearing. The Department must set a date for the hearing not less than 60 days from the date of the mailing or service, however a hearing may take place earlier upon agreement of all parties.

10.0 Hearing Process for License Denial and Compliance Actions

- 10.1 Hearings must be conducted according to the hearing provisions of the Administrative Procedure Act, 3 V.S.A. § 809-815.
- 10.2 The Commissioner's decision may be appealed to the Vermont Superior Court for the district in which the appellant is located. Appeals from the decision of the Superior Court must be to the Vermont Supreme Court.

11.0 Informing Patients of Investigation Completion

- 11.1 Upon completion of an investigation initiated upon a patient complaint, and determination as to whether an action is to be pursued under subsections 7.0 or 8.0 of this rule, the complainant or their representative must be provided notice in writing.
- 11.2 The notice must state that the investigation is complete and whether a public proceeding regarding the license of the subject facility has resulted.
- 11.3 Notice must be sent promptly and in no case more than 14 days after the determination is made and must include the time and place of any public proceeding.